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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte JOHN S. PATTON and ROBERT M. PLATZ

Appeal 2009-014575
Application 10/693,318
Technology Center 3700

Before DEMETRA J. MILLS, LORA M. GREEN, and
FRANCISCO C. PRATS, *Administrative Patent Judges.*

GREEN, *Administrative Patent Judge.*

DECISION ON APPEAL[1]

This is a decision on appeal under 35 U.S.C. § 134 from the Examiner's rejection of claims 2-39. We have jurisdiction under 35 U.S.C. § 6(b).

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[1] The two-month time period for filing an appeal or commencing a civil action, as recited in 37 C.F.R. § 1.304, or for filing a request for rehearing, as recited in 37 C.F.R. § 41.52, begins to run from the "MAIL DATE" (paper delivery mode) or the "NOTIFICATION DATE" (electronic delivery mode) shown on the PTOL-90A cover letter attached to this decision.

STATEMENT OF THE CASE

Claims 2 and 11 are representative of the claims on appeal, and read as follows:

2. An apparatus for producing aerosolized medicament, the apparatus comprising:

a reservoir containing a powder medicament to be aerosolized, the powder medicament comprising a protein or polypeptide; and

a chamber comprising first and second air inlets and a mouthpiece, wherein the first and second air inlets are oriented so that gas may flow in a vortical flow path in the chamber and may flow out of the chamber through the mouthpiece and wherein the flow of gas aerosolizes the powder medicament,

wherein at least 40 percent by weight of the powder medicament is suspended by the gas in the chamber for delivery through the mouthpiece.

11. An apparatus for producing aerosolized medicament, the apparatus comprising:

a reservoir containing a powder medicament to be aerosolized, the powder medicament comprising a protein or polypeptide; and

a chamber comprising first and second air inlets and a mouthpiece, wherein the first and second air inlets are oriented so that gas may flow in a vertical flow path in the chamber and may flow out of the chamber through the mouthpiece and wherein the flow of gas aerosolizes the powder medicament,

wherein the volume of the aerosolized medicament is from 9.24 percent to 21.5 percent of the volume of the chamber.

The following grounds of rejection are before us for review:

I. Claims 2, 5-7, 9-11, 14-16, 18-20, 23, 26, 27, 30, 31, 33, and 34 stand rejected under 35 U.S.C. § 103(a) as being rendered obvious by the combination of Calvert[2] and Saifer.[3]

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[2] Calvert, US 5,522,383, issued June 4. 1996.

II. Claims 3, 12, and 28 stand rejected under 35 U.S.C. § 103(a) as being rendered obvious by Calvert and Saifer as further combined with Morén.[4]

III. Claims 4, 8, 13, 17, 29, and 32 stand rejected under 35 U.S.C. § 103(a) as being rendered obvious by Calvert and Saifer as further combined with Hansen.[5]

IV. Claims 21, 24, 35-37, and 39 stand rejected under 35 U.S.C. § 103(a) as being rendered obvious by Calvert and Saifer as further combined with Abplanalp.[6]

V. Claims 22 and 25 stand rejected under 35 U.S.C. § 103(a) as being rendered obvious by Calvert and Saifer as further combined with Kirk.[7]

VI. Claim 38 stands rejected under 35 U.S.C. § 103(a) as being rendered obvious by Calvert, Saifer and Abplanalp as further combined with Hansen.

We affirm.

ISSUE

Has the Examiner established by a preponderance of the evidence that the claimed apparatus is rendered obvious by the combination of Calvert and Saifer?

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[3] Saifer, US 4,022,224, issued May 10, 1977.
[4] Morén, US 4,174,712, issued Nov. 20, 1979.
[5] Hansen, US 3,809,084, issued May 7, 1974.
[6] Abplanalp, US 4,396,152, issued Aug. 2, 1983.
[7] Kirk, US 4,860,740, issued Aug. 29, 1989.

FINDINGS OF FACT

FF1 The Examiner's statement of the obviousness rejection as to claim 2 may be found at pages 3-5 of the Answer.

FF2 Specifically, the Examiner finds that Calvert teaches an apparatus for producing an aerosolized medicine comprising a reservoir containing the powder medicament to be aerosolized; a chamber comprising first and second air inlets, and a mouthpiece, wherein the gas flows through the chamber through the inlet, aerosolizing the powder medicament, and out through the mouthpiece. (Ans. 4.)

FF3 The Examiner finds further that Calvert teaches "that the gas is introduced to the chamber at a swirl angle to create a vertical flow." (*Id.*)

FF4 The Examiner also finds that Calvert "explicitly disclose[s] that the device delivers as much of the medicament as possible." (*Id.*)

FF5 The Examiner further finds that as the apparatus of Calvert is the same as that required by claim 3, it "would be fully capable of delivering the claimed suspension amount." (*Id.* at 9.)

FF6 The Examiner finds further that while Calvert is silent as to the volume of the medicament aerosolized,

> absent a critical teaching and/or a showing of unexpected results from the volume of aerosolized medicament being 9.24-21.5% of the volume of the chamber, examiner contends it is an obvious design consideration to one of ordinary skill in the art to aerosolize a large range of medicament volumes, including 9.24-21.5% of the chamber volume, depending on the amount of medicament needed to treat the patient for a given condition and who is using the device (i.e., pediatric, adult).

(*Id.* at 4.)

FF7 The Examiner further notes, citing *In re Aller*, 220 F.2d 454, 456 CCPA 1955), that the "delivery of the claimed amount seems to be a mere optimization of workable ranges by routine experimentation that does not patentably distinguish an invention over the prior art of record." (Ans. 12.)

FF8 The Examiner notes that Calvert fails to specifically teach the use of a protein or polypeptide medicament. (*Id.* at 5.)

FF9 The Examiner relies on Saifer for teaching a protein, *i.e.*, orgotein, in the form of a powder for treating smoke inhalation. (*Id.*)

FF10 The Examiner thus concludes that it would have been obvious to use the orgotein of Saifer in the powder inhaler of Calvert because it would allow for the treatment of smoke inhalation. (*Id.*)

PRINCIPLES OF LAW

As to obviousness, the Supreme Court has emphasized that "the analysis need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ." *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (2007). "If a person of ordinary skill can implement a predictable variation, § 103 likely bars its patentability. (*Id.* at 417.)

ANALYSIS

Appellants argue that the Examiner has failed to set forth a prima facie case of obviousness as to claim 2. (App. Br.[8] 5.) First, according to Appellants, neither Calvert nor Saifer teaches or suggests that "at least 40 percent by weight of the powder medicament is suspended by the gas in the chamber for delivery through the mouthpiece." (*Id.* at 6.) Appellants further assert that the Examiner's finding "that '. . . the structure of Calvert et al. is the same as the instant invention and therefore would be fully capable of delivering the claimed suspension amount,'" is without merit, as the Examiner has offered "no basis or evidence for proffering that the structure of Calvert et al is the same as the instant invention." (Reply Br. 4 (alteration in original).) Appellants also argue that claim 2 is not drawn to the device alone, but to the device plus a powder medicament comprising a protein or polypeptide, and "prior to Appellant's invention powder medicaments comprising a protein or polypeptide had not been formulated and combined with an inhaler in a way that results in at least 40 percent by weight of the powder medicament being suspended in a chamber." (*Id.*)

Appellants argue further that Calvert only teaches that a high degree of emptying is desirable, but that "[d]esirability does not make something so." (App. Br. 6.) Appellants assert that "the Examiner offers no support for the contention that suspension of large amounts of powder would have been desirable." (*Id.* at 7.) According to Appellants:

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[8] All references to the Appeal Brief (App. Br.) are to the "Supplemental Appeal Brief" dated March 23, 2009.

> The achievement of 40% suspension for delivery through the mouthpiece, as recited in claim 2, is no small feat. Furthermore, all powders behave differently. A change in active agents within a powder will cause a change in powder characteristics. This change is likely to even be more exacerbated when going from a non-protein active agent to a protein active agent, which are difficult to suspend. Accordingly, the Examiner's apparent contention that by merely substituting the protein powder taught by Saifer et al for the powder used in Calvert et al would necessarily result in a system that meets the limitations of claim 2 is entirely without basis and is purely speculative.

(*Id.* at 6-7.)

Appellants' arguments have been carefully considered, but are not found to be convincing. As found by the Examiner, Calvert teaches all of the structural elements required by the apparatus set forth in claim 2: That is, Calvert teaches; (a) a reservoir containing a powder medicament to be aerosolized; (b) a chamber comprising first and second air inlets; and (c) a mouthpiece. (FF2.) As further found by the Examiner, Calvert teaches that the "first and second air inlets are oriented so that gas may flow in a vortical flow path in the chamber and may flow out of the chamber through the mouthpiece and wherein the flow of gas aerosolizes the powder medicament," as also required by claim 2. (FFs 2 and 3.) As also found by the Examiner, Calvert expressly teaches that the device delivers as much of the medicament as possible. (FF4.) Thus we agree with the Examiner that the ordinary artisan would have reasonably expected the device of Calvert to perform the same as the device set forth in claim 2, that is, would have reasonably expected that at least 40 percent by weight of the powder

medicament would be suspended by the gas in the chamber for delivery through the mouthpiece.

As to Appellants' arguments that the ordinary artisan would have expected different powders to behave very differently, we first note that Appellants claim 2 is very broad, encompassing any powder protein or polypeptide. In addition, while Appellants argue that the ordinary artisan would not have expected the powder protein medicament of Saifer to be able to be aerosolized to the extent required by claim 2, they present no evidence to that effect, and arguments of counsel cannot take the place of evidence in the record. *In re Scarbrough*, 500 F.2d 560, 566 (CCPA 1974). As noted above, Calvert teaches an apparatus for delivering a powder medicament that meets all of the limitations of claim 2, and Saifer teaches a powder medicament comprising a protein that meets all of the limitation of claim 2. Thus, again, we agree with the Examiner that the ordinary artisan would have reasonably expected that at least 40 percent by weight of the powder medicament taught by Saifer would be suspended by the gas in the chamber for delivery through the mouthpiece.

Appellants argue further that there is "no teaching, suggestion, or motivation to combine the teachings of the references." (App. Br. 7.) Appellants assert that the examples of Saifer suggest only using a nebulized or pressurized aerosol type of formulation, not a powder inhaler formulation, and thus the "dry powder preparation of Preparation 3 is ignored in the examples and this is clearly nothing more than a prophetic mention." (*Id.*) Appellants further assert that it would not have been obvious to select the device of Calvert among the numerous dry powder inhalers that were known

at the time of invention. (*Id.*) According to Appellants, the combination is thus based on impermissible hindsight. (*Id.*)

Appellants also argue that the rejection is improper as "the Examiner has not demonstrated that there was a known problem for which there was an obvious solution encompassed by the claims." (*Id.* at 8.) Rather, Appellants assert, "the teachings of the references give no indication that there was a problem associated with either teaching." (*Id.*)

Calvert teaches an apparatus for delivering a powder medicament that meets all of the limitations of the apparatus of claim 2, except for expressly teaching delivery of a protein or polypeptide powder medicament. Saifer teaches a protein medicament that can be delivered as a powder for treatment of smoke inhalation. Thus, we agree with the Examiner that it would have been obvious to the ordinary artisan to deliver the protein powder medicament of Saifer using the apparatus for delivering a powder medicament taught by Calvert. The fact that the combination of is one of a number of obvious combinations does not make it any less obvious. *KSR*, 550 U.S. at 419 ("What matters is the objective reach of the claim. If the claim extends to what is obvious, it is invalid under § 103.").

As to Appellants' argument that Saifer only teaches the preparation of the protein powder medicament, but does not specifically exemplify its administration, that argument is not convincing as the claimed invention is clearly suggested by the combination of Calvert and Saifer. A reference may be relied upon for all that it would have reasonably suggested to one having ordinary skill in the art, including non-preferred embodiments. *Merck & Co. v. Biocraft Labs.*, 874 F.2d 804, 807 (Fed. Cir. 1989).

Disclosed examples and preferred embodiments do not constitute a teaching away from a broader disclosure or non-preferred embodiments. *In re Susi*, 440 F.2d 442, 446 n. 3 (CCPA 1971).

Finally, as to claim 2, Appellants argue that the "ability to deliver high value medicaments such as proteins and polypeptides efficiently and effectively is both novel and unexpected, as discussed in the present specification on pages 1-4." (App. Br. 8.)

Again, Appellants' arguments are not found to be convincing. Pages 1-4 of the Specification is drawn to the background of the invention, and no data of any kind is presented, such as data comparing the claimed apparatus to the apparatus of the closest prior art. It is well settled that results must be established by factual evidence. Mere argument or conclusory statements do not suffice. *In re De Blauwe*, 736 F.2d 699, 705 (Fed. Cir. 1984).

Thus, we affirm the obviousness rejection of claim 2 over the combination of Calvert and Saifer.

As to the rejection of claims 5-7, 9, 10, and 20, Appellants rely on the arguments made with respect to claim 2. (App. Br. 9.) Thus, the rejection is affirmed as to claims 5-7, 9, 10, and 20 for the reasons set forth above with respect to claim 2.

As to claim 11, Appellants argue that neither of Calvert or Saifer "teaches a volume of aerosolized medicament that is from 9.24 percent to 21.5 percent of the volume of the chamber." (*Id.*) Appellants assert that the Examiner has "offered no teachings of parameters or variables that would lend themselves to directing the artisan towards a design that might result in Appellant's design." (*Id.* at 10.) Thus, Appellants assert, the instant

situation is distinguishable from *Aller* as "the general conditions of Appellant's invention are not disclosed in the prior art. Secondly, there are no process conditions that Appellant is adjusting for optimization." (Reply Br. 5.) Appellants also reiterate the arguments made above with respect to claim 2. (*See* App. Br. 10-11.) As to the rejection of claims 14-16, 18, 19, and 23, Appellants rely on the arguments made with respect to claim 11. (*Id.* at 11.)

Appellants' arguments are not convincing as discussed above in the analysis of claim 2, Calvert teaches an apparatus that meets all of the structural limitations of claim 11, thus the ordinary artisan would have reasonably expected the device of Calvert to perform the same as the device set forth in claim 11, that is, would have reasonably expected that the volume of the aerosolized medicament is from 9.24 percent to 21.5 percent of the volume of the chamber. Further, we agree with the Examiner that the ordinary artisan would understand that "[d]epending on factors such as the characteristics of the powder being delivered, the size and shape of the chamber, and the patient's presented condition and desired therapy, one of ordinary skill in the art would find it obvious to deliver the claimed volume by varying the above factors as needed to deliver the desired amount of medicament for treatment." (Ans. 12.) Thus, while the prior art may not explicitly teach what parameters that may need to be varied, the ordinary artisan would understand the parameters to be varied in order to deliver the desired amount of protein or polypeptide medicament to the patient.

We thus affirm the rejection as to claim 11, as well as to claims 14-16, 18, 19, and 23, as no separate arguments were presented as to those claims.

As to the rejection of independent claim 26, Appellants reiterate the arguments made above with respect to claim 2. (*See* App. Br. 12-13.) As to the rejection of claims 27, 30, 31, 33, and 34, Appellants rely on the arguments made with respect to claim 26. (*Id.* at 13.)

Thus, we affirm the rejection of claims 26, 27, 30, 31, 33, and 34 for the reasons set forth with respect to claim 2.

As to independent claim 35, Appellants reiterate the arguments made with respect to claim 2. (*See id.* at 15.) Appellants also assert that "one of ordinary skill in the art would not have found it obvious to combine the teachings of Abplanalp's propellant based dispenser with the dry powder inhaler of Calvert." (*Id.*) As to the rejection of claims 36, 37, and 39, Appellants rely on the arguments made with respect to claim 35. (*Id.* at 16.)

Appellants' arguments are not convincing. First, we rely on the analysis as set forth above with respect to claim 2. Second, the Examiner found that Abplanalp teaches "an aerosolizing device in which one air inlet is not oriented tangentially and a second inlet is not [sic] oriented tangentially to create a vortical flow for aerosolizing particles." (Ans. 7 (citing Abplanalp, col. 3, ll. 38-45.) Thus, we agree with the Examiner that it would have been obvious to use the teachings of Abplanalp to modify the apparatus of Calvert and Saifer as Abplanalp teaches that the claimed tangentially oriented air inlet and non-tangentially oriented air inlet and mouthpiece is known to create a vertical flow for aerosolizing particles. Appellants have not provided any argument or evidence that the orientation taught by Abplanalp would not be expected to create a vertical flow in the dry powder inhaler of Calvert.

We thus affirm the rejection of claims 35, 36, 37, and 39.

Appellants also argue with respect to rejections II-VI that none of Moren, Hansen, Abplanalp, and Kirk make up the deficiencies of the combination of Calvert and Saifer. (App. Br. 13-17.)

Those arguments are not convincing for the reasons set forth *supra*.

CONCLUSION OF LAW

We conclude that the Examiner has established by a preponderance of the evidence that the claimed apparatus is rendered obvious by the combination of Calvert and Saifer.

We thus affirm all of the rejections on appeal.

TIME PERIOD FOR RESPONSE

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

AFFIRMED

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